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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,715	09/18/2003	Dimitrios Manoussakis	P-5808	4404
26253 7590 08/10/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER				
WRIGHT, PATRICIA KATHRYN				
ART UNIT		PAPER NUMBER		
1797				
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08/10/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,715

Applicant(s)

MANOUSSAKIS ET AL.

Examiner

P. Kathryn Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-18, 20-24, 26-28 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16-18, 20-24, 26-28, 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. This action is in response to Pre-Appeal Brief conference decision filed July 27, 2009, which indicated that the previous rejections of the last official action are withdrawn. A new action on the merits follows.

Claims 1-13 and 33-86 remain withdrawn.

Claims 14, 16-18, 20-24, 26-28, and 30-32 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 14, 16-18, 20-24, 26-28 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hugh Conway (EP 1 107 002 A2), published June 13, 2001.

Conway teaches a container (tube 14) having an upper end 13, a closed lower end 14, and a sidewall 15 between the upper and lower ends 13, 14 having inner and outer walls 15a, 15b (see paragraphs [0022]). The tube includes a pierceable closure (stopper 18) therein.

Conway teaches a thixotropic gel 24 completely contained in deformable container or flexible bag 22. The bag 22 may be formed of materials which sufficient tackiness to promote adherence of the bag to the inner surface 15a of the tube to create first 22b and second 22a continuous regions seen in Figs. 1-3. The first region of the bag and gel is located at or adjacent the lower end 14a and the second region 22a extending upward from a portion of the first region 22b, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall 14a, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel. That is, as shown in the Figs. 1 and 2, the gel 24 substantially fills the first portion 22b of the bag 24 with only remaining second portion 22a being substantially absent of gel (see paragraph [0028]). Thus, it can be reasonably assumed that the first region of the gel comprises *at least about* 80 vol.% of the thixotropic gel.

Conway does not specifically disclose the gel in contact with a portion of the inner wall of the container. However, the use of thixotropic gel materials as a direct barrier for moving into an area adjacent the two phases of the sample being separated in order to maintain the components separated for subsequent examination of the individual components is well known in the art (see paragraphs [0002]-[0005] of Conway). The thixotropic gels used in separating blood components are typically chemically inert to most analytes present in blood samples. Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to eliminate the flexible bag from the device of Conway since the use of such bags increases the manufacturing cost and complexity of the device.

As to claim 16, it appears the imaginary upper boundary of Conway exhibits a best fit plane within 10 degrees of a plane perpendicular to the longitudinal axis of the tube, see Figs. 2-3.

Regarding claims 17-18, Conway is silent to the distance between the first and second regions being between 8 to 21 mm, however, it the claimed distance would have been obvious to one of ordinary skill in the art through routine experimentation in an effort to optimize the operational parameters of the device.

As to claims 20-24, it is reasonable to assume the first region 22b of Conway comprises about 80 to 95 vol. % of the gel (claim 20), the interior surface of the thixotropic gel at the intersection of the first and second regions exhibits a radius of curvature between about 4 and about 8 mm (claim 21), wherein a best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 25 ° or less with a plane substantially perpendicular to the longitudinal axis of the

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container (claim 22), the exposed surface of the second region facing the interior of the container defines a best-fit plane exhibiting a 45 to 90° angle with a plane substantially perpendicular to the longitudinal axis of the container (claim 23), the best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 90 to 140° with the best-fit plane to the surface of the second region facing the interior of the container (claim 24), wherein along a plane perpendicular to the longitudinal axis of the container located halfway between the average height of the exposed surface of the first region and the uppermost point of the second region (see Figs. 1-3).

As to claims 26-27, the second region 22a of Conway exhibits 80 to 140° circumferential contact with the inner surface, wherein the entirety of the second region exhibits less than 180° circumferential contact with the inner wall 15a and, wherein the entirety of the second region 22a exhibits less than 120° circumferential contact with the inner wall 15a, see in particular Figs. 1 and 2 of Conway.

Response to Arguments

6. Applicant's arguments with respect to claims 14, 16-18, 20-24, 26-28, and 30-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/
Examiner, Art Unit 1797